

REMARKS

Status of Claims

Claims 3-11, 17-19, 22-26 and 30-32 were canceled as drawn to non-elected inventions. Claims 1, 2, 12-16, 20, 21, and 27-29 are rejected. Claims 1, 2, 12-16, 20, 21, and 27-29 are pending.

The Rejection of Claims Under 35 U.S.C. § 103 Should Be Withdrawn

Claims 1, 2, 12-16, 20, 21, and 27-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,244,877 (Eenennaam) in view of U.S. Publication 2002/0151733 (Ulrich) and further in view of U.S. Publication 2002/0108148 (Boronat). The Examiner states that Eenennaam teaches methods for the production of transgenic plants, and that the disclosed transgenic plants may be processed to produce a feed, meal protein, or oil preparation designed for ruminant animals, rendering obvious the diet of Applicants' claim 1, and the methods of claims 12 and 13 (page 3 of the Office Action date 05/07/2010). Although the Examiner acknowledges that the prior art reference does not explicitly teach a feeding step, he concludes that it would be obvious to a person of ordinary skill in the art to feed a ruminant animal a feed, meal, protein, or oil preparation which is designed for ruminant animals since Eenennaam discloses, "[i]n a preferred embodiment the feed, meal, protein or oil preparation is designed for ruminant animals." Applicants respectfully traverse the Examiner's rejections of claims 1, 2, 12, 16, 20, 21, and 27-29 under 35 U.S.C. § 103(a).

Establishing a *prima facie* case of obviousness requires assessment of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), which provides the framework for applying the statutory language of § 103. Under the "Graham Factors," the Examiner is required to:

1. Determine the scope and content of the prior art;
2. Ascertain the differences between the prior art and the claims at issue;
3. Resolve the level of ordinary skill in the pertinent art; and
4. Consider any relevant secondary considerations.

Furthermore, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) requires that the combination of references places the claimed subject matter in the public domain prior to

Applicants' date of invention. See *In re Zenitz*, 333 F.2d 924, 142 USPQ 158 (C.C.P.A. 1964).

The instant claims recite a method of feeding a diet comprising at least 150 ppm of mixed tocotrienols or comprising 50 ppm to 500 ppm mixed tocotrienols. As outlined below, neither the use of "mixed tocotrienols" in a feed nor the concentration of the mixed tocotrienols (i.e., ppm in a feed) are taught or rendered obvious by *any* of the cited references.

Eenennaam *does not teach* the different concentrations of tocotrienols that would be present when the transgenic plants are converted to a feed, nor does the reference teach the use of such compounds in a feed. Eenennaam teaches the genetic modification of plants to increase one or more products of the tocopherol biosynthesis pathway, "including any one or more of tocotrienols, alpha-tocotrienols, gamma-tocotrienols, delta-tocotrienols, and beta-tocotrienols..." (Eenennaam paragraph 0222). Eenennaam does not teach ranges of tocotrienols for feed, much less the "mixed tocotrienols" as recited in the instant claims. See, page 6, lines 14-16 of the instant application where 'mixed tocotrienols' are defined as at least three of the four tocotrienols, with or without other components such as α -tocopherol. Moreover, Eenennaam does not teach any tocotrienol ppm ranges in a feed as taught by the instant application. Thus, the ppm range of the instant invention cannot be determined or derived from Eenennaam and *is not obvious*.

The Examiner asserts that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists in view of Eenennaam and further in view of Ulrich. However, contrary to the assertion by the Examiner, no such "overlap" of ranges occurs between the instant claims and disclosure of the cited references.

Ulrich teaches the extraction of oil using a specifically defined process. Ulrich teaches a range of 50-330 ppm for *α -tocopherol* and about 1000-3000 ppm of *γ -tocotrienol* in solvent-extracted corn oil or an increase of 10-17 fold of tocotrienol content over wet or dry, milled crude corn oil. These ranges disclosed by Ulrich relate to the concentration of the compounds in an oil *not* in a feed. In contrast, claim 1 recites a method of feeding a diet comprising at least 150 ppm of mixed tocotrienols. As stated on page 7, lines 23-24 of the instant specification, an animal "diet" comprises a formula providing adequate levels of all nutrients required by the animal species. Therefore, the oil taught by Ulrich is *not* a "diet" as recited in the instant claims.

This point is of particular relevance when considering the concentration of tocotrienols in the oil of Ulrich versus the concentration of mixed tocotrienols in the diet recited in the instant claims.

To calculate parts per million (ppm), several components are necessary:

1. the mass of the solvent in kilograms must be determined;
2. the mass of the solute in milligrams must be determined; and,
3. the mass of the solute is then divided by the mass of the solvent.

In light of how ppm is calculated, the range of mixed tocotrienols in an animal diet must be measured in the final "feed" or "diet" provided to the animal. In other words, Ulrich's disclosure of an oil having 50-330 ppm for *α-tocopherol* provides no commentary on the final concentration of the tocotrienol that would be present in a "diet". Thus, Ulrich provides no comment on the level of mixed tocotrienols in the feed of an animal diet.

This point is actually supported by Ulrich when discussing the how their extracted corn oils will be employed. Ulrich *et al.* explains:

...the specific ingredients included in a product will be determined according to the ultimate use of the product...Important to note is that starting with a single corn type (e.g., 4% by weight oil and 7.5% by weight protein), more than one corn meal type may be produced depending on the end product nutritional requirements by the process of the invention. The significance of the flexibility relates to the nutrient density within feed products and to dietary requirements of animals. (Paragraphs 0036 and 0037 of Ulrich, emphasis added).

Thus, Ulrich actually teaches that there are *not* a finite number of identifiable and predictable animal feeds, but rather that the desired end product nutrition requires addition of supplemental elements. In the instant claims, a very specific level of tocotrienols is recited in the diet, where the ppm range refers to the composition in a defined diet (as per the instant claims) and not that inherent to corn oil.

The Examiner states that Eenennaam discloses that "[t]here is a...need for transgenic organisms expressing...nucleic acid molecules involved in tocopherol biosynthesis, which are capable of nutritionally enhancing food and feed sources;" and that the improved tissue quality produced by the instant claims 1 and 20 and the oxidative stability derived from instant claims 2 and 21 are inherent features of tocotrienols as shown by Boronat (page 5 of the Office Action date 05/07/2010). We disagree.

As outlined above, Eenennaam does not teach the feed composition claimed by the instant invention. Moreover, Boronat only generally mentions that "tocopherols and tocotrienols... are well-known antioxidants..." while referring to their (tocopherols and tocotrienols) effects on humans. Boronat *does not teach* a composition or range of tocotrienols in animal feed or their effects on animal tissue quality for commercial production. Furthermore, Boronat groups *all* isoprenoids (tocopherols and tocotrienols) together as tocopherols or vitamin E and does not teach differences between these anti-oxidants. It is important to note that vitamin E or α -tocopherol differs structurally from the tocotrienols. In the instant invention, a distinction is made between the tocopherols and the tocotrienols, where the mixed tocotrienols comprises a defined amount of tocotrienols. Therefore, it is not obvious to try the composition of the feed with the specifically defined mixed tocotrienol levels taught by the instant invention.

In re O'Farrell specifies that there are at least two circumstances in which what was "obvious to try" is not necessarily obvious. Under the first circumstance, a claimed invention may not be obvious when what "would have been 'obvious to try' involves varying all parameters or trying each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *Id.* Under the second circumstance, a claimed invention may not be obvious when "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.* Based on these criteria and the facts set forth above, Applicants maintain that feeding a diet comprising a specific supplement is *NOT* obvious over feeding the products taught by Eenennaam and Ulrich, in that the end product is *NOT* the result of choosing from a finite number of identified, predictable solutions with a reasonable expectation of success. A motivation to search for a specific composition with known properties does not make the claimed composition obvious unless the prior art suggests the specific composition and modifications necessary to achieve that which is claimed. See, *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008).

In view of the arguments set forth above, a *prima facie* case of obviousness under § 103 has not been made, and Applicants respectfully request that the Examiner withdraw the

rejection.

Although Applicants do not concede that a *prima facie* case of obviousness has been established for claims 1, 2, 12-16, 20, 21, and 27-29, even if established, evidence of secondary considerations such as unexpected results or unforeseen advantageous properties of the claimed composition, relative to that of the prior art, can rebut a *prima facie* case of obviousness. See *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987); *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Applicants respectfully remind the Examiner that the secondary consideration of unexpected or superior results obtained with an invention provides objective indicia of nonobviousness. See, for example, *In re Mayne*, 104F.3d 1339, 1342, 41USPQ2d 1451, 1454 (Fed. Cir. 1997) and *In re Woodruff*, 919F.2d 1575, 1578, 16 USPQ2d 1934,1936-37 (Fed. Cir. 1990).

Applicants draw the Examiner's attention to Examples 2 and 3 of the instant application, where unexpected results were obtained. The data demonstrates that supplementation with the instant invention at 150 and 300 ppm decreases the concentration of thiobarbituric acid reactive substances (TBARS) in the meat. TBARS is a measurement of oxidative stability and is an indicator of meat quality. See, Table 3 of the instant application; days 16 and 7, respectively and Table 8, day 10. Such supplementation also decreases loin purge compared to tocopherol (α - and/or γ -tocopherol) addition alone. See, Table 5 of the instant application. Therefore, feeding a diet embodied by the instant claims improved animal tissue quality and shelf life, over feeding with tocopherols alone. Thus, the diet recited in the instant claims demonstrate unexpected and superior properties such that feeding a diet with 50-500 ppm of mixed tocotrienols was more beneficial than feeding a diet with tocopherols alone. Such "secondary considerations" support the conclusion that the rejected claims are not obvious.

In view of the remarks and arguments set forth above, Applicants respectfully request that the rejection under U.S.C. 35 § 103(a) be withdrawn and place the claims in condition for immediate allowance.

The Rejection of Claims Under 35 Nonstatutory Double Patenting Should Be Withdrawn

I. Claims 1, 2, 12, 13, 14-16, 20, 21, and 27-29 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of co-

pending Application No. 11/153,463. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other as the claims of Application No. 11/153,463 claim a method of improving the tissue quality of an animal, including ruminant animals, using mixed tocotrienols. Applicants traverse this rejection and respectfully request that the Examiner consider the following remarks.

The burden of establishing a *prima facie* case of double patenting of the obviousness type lies with the Examiner. The Examiner should make clear:

- (A) The differences between the inventions defined by the conflicting claims;
- (B) The reasons why a person of ordinary skill would conclude that the invention defined in the claim(s) at issue is anticipated or would have been an obvious variation of the invention defined in a claim of the patent.

Importantly, when considering whether the invention defined in a claim of the application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used a prior art. *General Foods Corp. v. Studiengesellschaft Khole mbh*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). The specification can be used as a dictionary to learn the meaning of a term in the patent claim. *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). Furthermore, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent application may be considered.” *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970).

The '463 application does not teach all of the elements of the present invention. Applicants' independent claims 1 and 20 recite a method of improving the tissue quality of an animal, comprising feeding the animal a diet comprising mixed tocotrienols.

In contrast, the claims of the '463 application recite a method of improving the tissue quality of an animal comprising feeding the animal a diet comprising *oleic acid and selected tocots*. The "selected tocots" are defined in the '463 application as "one or more of the tocotrienols (TT), gamma-tocopherol (GT) or a mixture of at least one tocotrienol and gamma-tocopherol." See

'463 Application, p. 1, paragraph [0009]. The claims of '463 application do not teach or suggest a method of improving the tissue quality of an animal comprising feeding the animal a diet of mixed tocotrienols, as required by claims 1 and 20 of the instant invention. As discussed *supra*, "mixed tocotrienols" is defined in the specification as "any mixture that contains at least three of the four known tocotrienols". See the instant specification, page 5, lines 10-11 (emphasis added).

The claims of '463 application accordingly do not teach all of the limitations of independent claims 1 and 20. Therefore, the provisional rejection of claims 1, 2, 12, 13, 14-16, 20, 21 and 27-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of the '463 application should be withdrawn.

II. Claims 1, 2, 12, 13, 14-16, 20, 21, and 27-29 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of co-pending Application No. 11/520,075. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other as the claims of Application No. 11/520,075 claim a method of improving the tissue quality of an animal, including ruminant animals, using mixed tocotrienols.

The '075 application does not teach all of the elements of the present invention. Applicants' independent claims 1 and 20 recite a method of improving the tissue quality of an animal, comprising feeding the animal a diet comprising mixed tocotrienols.

In contrast, the '075 application claims a method of improving the meat quality of an animal comprising feeding the animal a diet comprising oleic acid, tococls and a non-tocol anti-oxidant. The claims of the '075 application do not teach or suggest a method of improving the tissue quality of an animal comprising feeding the animal a diet of mixed tocotrienols, as required by independent claims 1 and 20. As discussed *supra*, "mixed tocotrienols" is defined in the specification as "any mixture that contains at least three of the four known tocotrienols". See specification, page 5, lines 10-11 (emphasis added).

The claims of the '075 application accordingly do not teach all of the limitations of independent claims 1 and 20. Therefore, the provisional rejection of claims 1, 2, 12, 13, 14-16, 20, 21 and 27-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable

over claims 1-20 of the '075 application should be reversed.

CONCLUSION

It is believed that all the rejections have been obviated or overcome and the claims are in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject applications, the Examiner is invited to call the undersigned agent.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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